



August 9, 2001

9607 01 1000
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket No. 98N-0337

APPLICATION FOR DEFERRAL

Re: Request for Deferral from 21 CFR 201.66 (OTC Drug Product Labeling)
Subject: L. Perrigo Company (Perrigo)
Day Time Liquid-Filled Capsules (Perrigo product code 389)

Statement of Purpose

Pursuant to 21 CFR 201.66(c), Perrigo requests a Deferral from 21 CFR 201.66 for its Day Time Liquid-Filled Capsule over-the-counter drug product (Perrigo product code 389). On October 6, 2000 Perrigo requested that the Food and Drug Administration permit the use of the phrase "May contain" on the product label to reflect those inactive ingredients that may differ in the formulas manufactured by two suppliers. This request was filed as an Exemption from 21 CFR 201.66(c)(8). To date, Perrigo has not received a response from the FDA regarding the Exemption Request. Perrigo understands that this is a complex matter still under review at the agency. However, Perrigo must still be in a position to comply with the regulation by May 16, 2002.

Setting

Perrigo is the nation's largest manufacturer of over-the-counter (OTC) pharmaceutical products for the store brand market. These products are sold by retail supermarkets, drugstores and mass merchandise chains under their own labels.

Request

Due to the number of SKUs for this product, it is impracticable for Perrigo to reasonably maintain two labeling versions for each retail customer. Therefore, Perrigo must request a Deferral from 21 CFR 201.66 for Day Time Liquid-Filled Capsules pending the outcome of the Exemption Request or Citizen Petitions submitted by Arnall, Golden, Gregory LLP and the Consumer Healthcare Products Association currently under consideration by the FDA. The OTC Labeling Final Rule requires compliance by May 16, 2002 for this product. However, due to the time needed to change labeling specifications, develop customer-specific art, obtain customer approval, print labeling components and label finished product, it is necessary that Perrigo initiate a labeling conversion now in order to convert this product by the compliance date. The Deferral would remain in effect for an estimated nine months following the FDA response(s) to the pending Exemption Request or Citizen Petitions. If the Deferral were granted, consumers would continue to buy safe and effective products without undue additional costs. Granting the Deferral would also allow additional time for the FDA to consider the impact of the Exemption Request while allowing Perrigo to avoid additional labeling conversions.

98N-0337 515 Eastern Avenue
Allegan, Michigan 49010
(616) 673-8451

APP 31



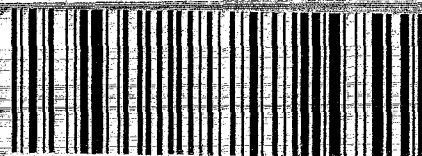
If there are any questions concerning this request, please contact me by phone at (616) 673-7595 or fax at (616) 673-7655. Thank you for your attention to this matter.

Sincerely,
L. PERRIGO COMPANY

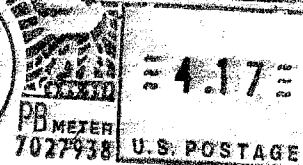
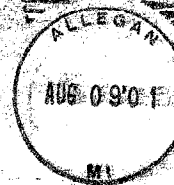
A handwritten signature in cursive script, appearing to read 'D. Jespersen'.

David Jespersen
Director of Technical Affairs

CERTIFIED MAIL



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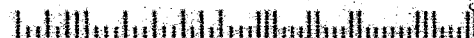


Request for Exemption from 21 CFR 201.66
(OTC Labeling format)

Docket no. 98N-0337
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5630 Fishers Lane, Room 1061
Rockville, MD 20852

WFA-305

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